

Medi-Khan(USA) Inc.

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Indications for Use

510(k) Number (if known):

Device Name: Lipokit with disposable 50cc AFT Syringes

Indications for Use:

The Lipokit is used in the tumescent injection, aspiration, harvesting, filtering and transferring of autologous fat tissue.

The Lipokit is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

- Plastic and Reconstructive Surgery
- General Surgery
- Dermatological Surgery
- Obstetrician & Gynecological Surgery
- Cosmetic Surgery

The Lipokit is indicated for use when harvesting of highly concentrated pure fatty tissues for aesthetic body and facial contouring is desired.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE --CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Knoke, Jr., M.D.
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083455